

Combating Deception in Dietary Supplement Advertising

Remarks By Commissioner Sheila F. Anthony

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I. Introduction

Thank you for that introduction and congratulations to those who received awards. I am delighted to be here this afternoon to discuss a subject in which I am most interested.

The agenda for this conference covers a lot of territory, but my presentation will focus only on the Commission's role in the dietary supplement area.

Before I begin, and as a courtesy to my FTC colleagues, I want to remind you that the views I express are my own and do not reflect those of the Commission or any individual Commissioner.

Today I will:

- Highlight recent Commission law enforcement initiatives in the dietary supplement area;
- Describe the Commission's consumer and business education efforts as well as our media outreach efforts; and
- Urge industry to take a more active role in self-regulation.

Following the dramatic regulatory changes of The Dietary Supplement Health and Education Act ("DSHEA"),¹ we saw an equally dramatic increase in the marketing of supplements and, with that increase, we have seen more examples of questionable claims. FDA and FTC now face many challenges in policing the dietary supplement industry. As you probably know, the FTC has primary responsibility for enforcing truth in advertising, while the FDA has primary responsibility for labeling claims. The vast majority of labeling claims about the safety and efficacy of dietary supplements are not subject to pre-market review by the FDA. Therefore, the burden is on FDA to show, **after** the product is on the market, that a dietary supplement is either unsafe or ineffective. That is a difficult task given the volume of products and promotions in the marketplace.

II. Recent Commission Law Enforcement Initiatives

Under the FTC Act, dietary supplement manufacturers must be able to substantiate all performance, efficacy and safety claims in advertising **before** they are made. Misleading or unsubstantiated claims in dietary supplement advertising constitute a large and growing part of the FTC's enforcement agenda.² Our law enforcement plate is very full as a result of the explosion in growth of the dietary supplement industry. Two

¹ 21 U.S.C. Section 321 *et seq* (1994).

² Our authority in this area in this area derives from Section 5 of the FTC Act, which prohibits "unfair or deceptive acts and practices in or affecting commerce," and Section 12, which prohibits the false advertisement of "food, drugs, devices, services or cosmetics." 15 U.S.C. Sections 45, 52.

factors have had a significant influence over this growth. The Internet has made it easier for snake oil salesmen to sell their products because it allows marketers, both large and small, to go global. In addition, many dietary supplement marketers believe that DSHEA provides a green light to make implied health and disease claims and avoid FDA review or approval. Consequently, the Commission has seen its workload expand in recent times in policing dietary supplement advertising. The Commission has brought over 60 law enforcement actions in the past 5 years challenging false or unsubstantiated claims about the efficacy and safety of a wide variety of dietary supplements, and we have many more in the pipeline.

I will describe some of the Commission's law enforcement activities, focusing on two areas: remedies and liability.

A. Remedies

Given that the vast number of potential targets exceeds our limited resources, the Commission attempts to ensure that it obtains appropriate relief in the actions we bring. In the first instance, whether we proceed administratively or in district court, we seek injunctions prohibiting the future use of false or unsubstantiated claims at issue. Our orders require substantiation for all claims made, but require "competent and reliable scientific evidence" for claims involving health, safety, or efficacy.

In appropriate cases we also seek monetary relief in the form of consumer redress or disgorgement of ill-gotten gains. Sometimes we also require a performance bond. Let me give you two relatively recent examples. The marketers of a product called Slim America ran full page ads in magazines like *Ladies Home Journal*, *McCall's*, and *Cosmopolitan* claiming its chromium picolinate supplement would "blast" up to 49 pounds off in only 29 days. The Commission sued Slim America³ in federal court and ultimately obtained an \$8.3 million judgment that represented the company's total sales. In addition, we required the individual behind the marketing of the product to post a \$5 million performance bond before engaging in any new weight loss advertising ventures.

In another district court matter, Enforma Natural Products, Inc. ("Enforma")⁴ ran an infomercial promising that its two products would result in substantial weight loss even for those indulging in high fat foods. "Fat Trapper" is a chitosan-based product that purports to prevent the absorption of dietary fat. The other product, "Exercise in a Bottle," contains pyruvate that supposedly increases the body's capacity to burn fat. Specifically, Enforma claimed that its system "helps your body to burn more calories while you're just standing or sitting around doing nothing – even while you are sleeping." And "You can enjoy all these delicious foods like fried chicken, pizza, cheeseburgers, even butter and sour cream, and stop worrying about the weight." Now, these claims are too good to be true, and they weren't.

³ See *FTC v SlimAmerica, Inc.*, No. 97-6072-Civ (S.D. Fla. 1999).

⁴ See *FTC v Enforma National Products, Inc.*, No. 04376JSL(CWx) C.D. Cal. April 26, 2000).

In settling this matter, the Commission obtained \$10 million to be used for consumer redress. However, we continue to have concerns about the marketing of the Enforma products and have initiated contempt proceedings against Enforma in which we are seeking all revenues for the products since the date of our initial consent. I will come back to Enforma in a few minutes when I talk about liability.

The Commission's recent enforcement actions also demonstrate that the safety of supplement products is a priority for the agency. A number of our recent cases have focused on serious health risks raised by the promotion of supplements that are either inherently dangerous or that present a risk for interactions or other side effects. In all of these cases we have coordinated our actions closely with FDA. For example, last year, the Commission entered into two settlements with companies selling comfrey, an herbal supplement, for internal use with claims that the product was safe. In fact, comfrey is known to be highly toxic to the liver, and our orders banned the future sale of the herb for internal use or on open wounds. In addition, we required a strong warning to accompany all labeling and advertising of comfrey products. Our action coincided with FDA's alert to industry to remove comfrey from all supplement products.⁵

In two other matters involving the marketing of St. John's Wort,⁶ the Commission challenged ads claiming that consumers could safely use the product to treat a variety of diseases, including AIDS, TB, and Hepatitis B. The ads also falsely claimed that ingestion of the product had no known contraindications.

The Commission's settlement with Panda Herbal International, Inc., ("Panda") required Panda to issue a warning on all labeling and advertising alerting consumers to the dangerous interactions St. John's Wort has with certain prescription drugs and recommending that consumers consult a physician before taking St. John's Wort with certain kinds of drugs. In addition, the settlement required Panda to send a notice to all purchasers of the product informing them of the Commission's settlement, and offering full refunds.

As these examples illustrate, we attempt to make certain that in the actions we take, the relief we obtain is as comprehensive as necessary to protect the public.

B. Liability

In keeping with our effort to obtain strong relief in our cases, we are also looking broadly at the question of who has liability for deceptive advertising claims. As we emphasized in the FTC's Dietary Supplement Advertising Guides issued in 1998,

⁵ See *FTC v. Western Botanicals, Inc.*, No. CIV.S-01-1332 DFL GGH (E.D. Cal.) stipulated final order filed July 11, 2001); and *FTC V Christopher Enterprises, Inc.* No. 2:01 CV-0505 ST (D. Utah) (stipulated preliminary injunction filed July 3, 2001.)

⁶ See *Panda Herbal Int'l, Inc. C-4018* and *ForMOre, Inc., C-4021* (Aug 3, 2001).

... all parties who participate directly or indirectly in the marketing of dietary supplements have an obligation to make sure that claims are presented truthfully and to check the adequacy of the support behind those claims.⁷

No marketer should assume that it can simply rely on the safety or efficacy claims of the manufacturer no matter how implausible, and pass them on to the public without liability.

I'd now like to spend a few minutes talking about liability of the 1) advertiser, 2) ad agency, and 3) expert or celebrity endorser. I know you know that advertisers are responsible for all claims, express and implied, that are reasonably conveyed by an ad.

Advertising agencies will share liability if the agency was an active participant in the preparation of the ad, and if it knew or should have known that the ad was deceptive. Just last month, the Commission announced a settlement with Interstate Bakeries, the marketers of Wonder Bread, and its ad agency, Campbell Mithun LLC, for making unsubstantiated claims about Wonder Bread.⁸ The ads represented that the calcium in Wonder Bread helps children's minds work better and helps their memory. Our complaint alleged that Interstate Bakeries did not have adequate substantiation to make such health claims for Wonder Bread. By also naming the ad agency, Campbell Mithun, the Commission asserted that the ad agency knew or should have known that the claims were not substantiated, and therefore shared liability for the deceptive claim.

Other parties such as catalog marketers, retailers, infomercial producers, and TV home shopping companies as well as expert or celebrity endorsers can be liable for their roles in disseminating deceptive claims. In August, the Commission accepted a settlement with Value Vision International, Inc.,⁹ the third largest television "home shopping" network to resolve allegations that it disseminated deceptive claims for weight loss, cellulite, and baldness products. Value Vision was not the manufacturer of the products, but was essentially the "on air" catalog for a number of health-related products. The Commission found that Value Vision "knew or should have known" that the claims made for a variety of health-related products could not possibly be true and were, in fact, unsubstantiated.

To illustrate liability of celebrity endorsers, I direct you to our pending litigation with former baseball great, Steve Garvey.¹⁰ As I described earlier, the Commission entered into a stipulated judgment with Enforma, the marketer of weight loss products, chiefly promoted via a 30-minute TV infomercials. Steve Garvey acted as a celebrity endorser of the products on the infomercial. Our complaint against Garvey alleges that he had an active role in developing the deceptive claims made to sell Enforma System's two dietary supplements – chitosan-based "Fat Trapper" and pyruvate-based "Exercise In a Bottle."

⁷ See *Dietary Supplements: An Advertising Guide for Industry* 1998, p. 2.

⁸ See Interstate Bakeries, File No. 0123182, and Campbell Mithun, LLC, File No. 0123182 (March 6, 2002)/

⁹ See, Value Vision International, Inc., C-4022 (Aug. 24 2001).

¹⁰ See, *FTC v Steve Garvey*, (Civil Action No. 00-09358-AHM (AIJx) (September 1, 2000)

As I noted, this case is still in litigation and the bench trial was held in March. We will have to wait to see how the court will treat this matter.

To further ensure that Enforma's products and similar weight loss supplements would not be deceptively marketed to consumers, the Commission also sent advisory letters to 45 other marketers of weight loss products containing the same ingredient – chitosan. Nearly half of those marketers have already indicated to staff that they would stop marketing the product or remove the questionable claims. And finally, the Commission contacted major retail chains that carried the Enforma products to alert them to the FTC order and to make them aware of their potential liability if they participated in the deceptive marketing.

But for all of our law enforcement successes, we face many hurdles. Some marketers simply move outside the country, but continue to market in the US. A troubling example is the recent, and so far unsuccessful, effort to stop the marketing of the weight loss pill "Maxiline." The product was promoted heavily in full-page ads in the Sunday paper coupon inserts. Claims included "Sleep ... and lose weight in just a few nights ... you eat whatever you want." The marketer's highly unscientific explanation is that the body's fat cannot defend itself from attack while asleep. The Commission was able to obtain a temporary restraining order against the unknown parties behind the campaign.¹¹ Unfortunately, after many hours of investigation, dozens of subpoenas and even assistance from authorities in Canada, where much of the money was directed, staff has reached an impasse, unable even to identify or locate the responsible individual or corporation.

III. Consumer/Business Education and Media Outreach

The Commission supplements its law enforcement actions with business and consumer education activities. In 1998, the Commission issued *Dietary Supplements: An Advertising Guide for Industry*. The Guide clarifies FTC advertising law and how it relates to the requirements of DSHEA. It provides a detailed discussion of what advertisers must do to comply with the requirements that advertising claims be substantiated by competent and reliable scientific evidence, and uses specific examples from the supplement industry to illustrate and educate.

The Commission has undertaken an extensive consumer education campaign and has published several consumer education brochures on diet, health and fitness, including many specifically on weight loss. Our web site also links to many education materials developed by the Partnership for Healthy Weight Management, a coalition composed of representatives from science, academia, the health care professions, commercial enterprises, and public interest groups.

¹¹ See *FTC v. One or More Unknown Parties Falsely and Deceptively Advertising the Weight-Loss Product Known as Maxiline*, Docket No. 00-3035 (ESH) (D. D.C.).

I mentioned earlier that I believe that the Internet has helped fuel the growth of misleading and deceptive dietary supplement advertising by some of the industry's snake oil salesmen. One of the ways the Commission attempts to deal with that is through our "surfs." Our staff, together with other law enforcement agencies, conducts Internet surfs by searching for specific disease claims. When we find a site making dubious therapeutic claims, we send an email advisory to the website alerting it to the questionable nature of certain claims. The email also provides links to resources to help the site determine if it is in compliance with the law. Later, staff checks back and finds one of three things: the site is gone, the site modified its claims, or the site has ignored us. In some cases, those that have ignored our warning become law enforcement targets.

Many egregious claims -- particularly for weight loss products -- often appear in the mainstream media. Major national newspapers, magazines, television, cable and radio stations seem too ready to accept the substantial advertising dollars of this industry without question, often airing patently fraudulent ads with claims of extreme, instant and effortless weight loss. In recent years, the Commission staff has met on many occasions with various segments of the media and with individual publishers to discuss the need for better advertising clearance standards to screen out such facially false claims. The FTC has also published and distributed a booklet called, *Screening Advertisements: A Guide for the Media*. The Guide provides tips on screening deceptive ads, including buzz words and phrases that often appear in particular kinds of false advertising. Unfortunately, the response from the media has been at best, lukewarm. While many publications screen ads for taste and appropriateness they appear reluctant to take a few extra steps to weed out obvious fraud.

Several years ago, the FTC in conjunction with the Partnership for Healthy Weight Management, initiated its "Ad Nauseam Campaign" in an attempt to spur media screening efforts. The campaign publicly identified several examples of weight loss ads making fraudulent claims and the media outlets in which they ran. Ads promising as much as 93 pounds of quick and easy weight loss without dieting, ran in magazines like *Cosmopolitan*, *Esquire*, *McCall's*, *Redbook*, and *Women's Day*, in major newspapers like the *Atlanta Journal-Constitution*, the *Denver Rocky Mountain News*, and *USA Today* as well as "Smart Source," a coupon insert publication. Staff sent the offending ads to each of these publications with a letter urging them to take greater responsibility and to question advertisers before accepting such ads. Only *USA Today* provided any response.

IV. Industry Stepping Up to the Plate

The American public needs industry to help us combat advertising fraud! As you can see, the Commission uses a variety of means to combat deceptive claims for dietary supplements. But, more needs to be done. I believe that there needs to be more and better self regulation in the dietary supplement industry. The industry must step up to the plate and take a more active role in policing those in their industry who are engaged in fraud and deception, and are giving the entire industry a black eye.

The National Advertising Division (“NAD”) of the Council of Better Business Bureaus, created in 1971, is a model of an effective self-regulatory scheme that works and has the respect of industry. The NAD quickly investigates complaints against advertisers brought by both consumers and other advertisers. If an advertiser disagrees with the decision, it can appeal to the National Advertising Review Board, which has members from both inside and outside the advertising industry. One of the hallmarks of the NAD self regulatory scheme is that all decisions are made public which enhances the credibility of the program and provides valuable information to the public. The Children’s Advertising Review Unit is an example of a specialized segment of NAD focusing on children’s advertising. Why isn’t there a similar program devoted to dietary supplements advertising?

I also believe that the media has an exceptionally important role to play through media screening of problematic ads. Newspapers, magazines, radio, and cable TV should follow the lead of the major networks and responsible print media and refuse to run or promote those ads that, on their face, promise incredible results. The number of media outlets is proliferating and national advertising is appearing in newer media. Our recent law enforcement experience suggests that some media members are not paying close enough attention to the ads that are being run. I hope that the media also steps up to the plate and chooses to forgo placing ads that result in a fraud on the public, who, after all, are their customers too.

V. Conclusion

Our consumer protection mandate can be daunting in the face of the endless variety and volume of deceptive claims about the safety and efficacy of dietary supplements. Chasing purported cancer and AIDS cures on the Internet, alone, could consume all of our resources. We obviously must make some difficult choices in selecting cases to prosecute. Many of our efforts have been directed at the most obvious frauds, for the most deadly diseases, and on products that present serious safety concerns. We must continue to bring these cases, but I worry that as a result there are many unsubstantiated product claims that are going unchallenged. However, I caution those that assume that they are immune to an enforcement action as long as they don’t sell dangerous products or cancer cures. We are watching all advertising media – not just the Internet, but direct mail, infomercials, coupon inserts, talk radio and national newspapers, and we are seeing questionable claims everywhere we turn.

It has been a pleasure to be here today. I hope I have left you with some supplements for thought, and that you will use the FTC as a resource for guidance if you have questions about the advertising claims you are making. We are eager to help you comply with the laws our agency is tasked with enforcing. As the adage goes, an ounce of unsubstantiated ad claim prevention is worth more than a pound of legal defense costs cure.

Thank you.